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Court Documents Show GlaxoSmithKline Knew — for 40 Years — Zantac Could Cause Cancer

Amid tens of thousands of lawsuits that are pending in state courts all across the U.S., a new report based on evidence discovered in these court cases reveals Big Pharma giant GlaxoSmithKline had, for decades, concealed evidence showing that Zantac could cause cancer.

By **Michael Nevradakis, Ph.D.**

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Amid tens of thousands of lawsuits that are pending in state courts all across the U.S., a new report based on evidence discovered in these court cases reveals Big Pharma giant GlaxoSmithKline (GSK) had, for decades, concealed evidence showing that Zantac could cause cancer.

According to Bloomberg Businessweek, GSK — then known as Glaxo — had been aware of cancer-causing risks with ranitidine, the drug which was marketed as Zantac, even before it was approved by the U.S. Food and Drug Administration (FDA) in 1983. These warnings came from independent researchers but also from Glaxo scientists.

Within five years, Zantac, used to treat or relieve heartburn, acid indigestion and gastric ulcers, became the world's best-selling medicine and was one of the first to surpass $1 billion in annual sales, according to Reuters. GSK later sold the drug to Pfizer — and Zantac was then sold to Boehringer Ingelheim and finally Sanofi.

In 2019, an online pharmacy detected high levels of a potent carcinogen, NDMA, in Sanofi and its generic equivalents. This led to recalls, followed by a formal FDA withdrawal of the drug in 2020.

This decision was made based on "research showing the amount of NDMA in the products increases the longer the drug is stored and could potentially become unsafe," Reuters reported, with Fierce Pharma adding that this problem was identified "even under normal storage conditions."

According to the Bloomberg Businessweek report, the storage issues came in addition to the known risk that "under certain conditions in the stomach, ranitidine could form a potentially dangerous compound" that could cause cancer.

All four aforementioned pharmaceutical companies are now facing tens of thousands of lawsuits in state courts throughout the U.S. "Plaintiffs said the companies knew, or should have known, that ranitidine posed a cancer risk and that they failed to warn consumers," reports Reuters.

According to Reuters, "While NDMA is found in low levels in food and water, it is known to cause cancer in larger amounts." Zantac, accordingly, has been linked "to at least 10 types of cancer" in lawsuits that have been filed, including bladder, esophageal, liver, pancreatic and stomach cancers.

GSK continues to claim that there is "no consistent or reliable evidence" that Zantac caused cancer.

What is NDMA?

According to Bloomberg Businessweek, "NDMA, which is short for N-Nitrosodimethylamine, is a yellow liquid that dissolves in water. It doesn't have an odor or much of a taste." It is most toxic to the liver, and "was first linked to cancer in 1956."

It adds that "The carcinogen, called NDMA, was once added to rocket fuel and is now used only to induce cancer in lab rats."

The same report notes that NDMA is "one of a group of chemicals called nitrosamines, which by the 1970s were considered the most potent carcinogens yet discovered. They caused cancer in every species of animal tested. A single dose of less than a milligram of NDMA can mutate mice cells and stimulate tumors, and 2 grams can kill a person in days."

According to USA Today, drawing on FDA data, "Nitrosamines are found in water, cured and grilled meats, dairy products and vegetables" and studies have found that they lead to "increased cancer risk if people are exposed to large amounts over long periods of time."

Stephen Hecht, Ph.D., a professor of cancer prevention at the University of Minnesota, told USA Today that food safety experts have made efforts to reduce nitrosamine levels in foods such as cured meats to far below the levels of the 1970s and 1980s.

Bloomberg Businessweek states that "Every public-health agency, from the Environmental Protection Agency to the FDA to the World Health Organization, says NDMA likely causes cancer in humans."

The FDA has placed limits on six types of nitrosamines, reports USA Today, equaling "up to one case of cancer per 100,000 people exposed to the contaminant."

However, the drugs that were recalled and ultimately pulled from the market far exceeded these limits, with estimates of a risk of one cancer case for every 3,000 to 8,000 patients, according to USA Today.

The withdrawal of Zantac and its generic versions resulted in tens of thousands of lawsuits that are still pending — and a process of discovery that has unearthed significant evidence revealing that Glaxo and regulatory bodies were long aware of the presence of NDMA in these medications.

Discovery reveals that Glaxo, regulators continuously ignored NDMA cancer risk

Bloomberg Businessweek reviewed "thousands of pages" of documents, including those arising from the discovery process in the ongoing lawsuits against GSK and other drugmakers, as well as scientific studies, to develop its story, discovering that GSK supported "flawed research" that skewed the narrative away from Zantac's risks.

As stated in the Bloomberg Businessweek report: "Proving that a particular person's cancerous cells were mutated by a company's drug is complicated. Glaxo's decisions suggest it never wanted to consider that possibility. The clues were there. The documents show that Glaxo preferred not to find them."

The report continued:

> "From ranitidine's beginning to its end, Glaxo had been warned by its own scientists and independent researchers about the potential danger. An account of those four decades emerges in hundreds of documents, thousands of pages, many of which have never been made public.
>
> "Bloomberg Businessweek reviewed court filings, many still under seal, as well as studies, FDA transcripts and new drug applications obtained via Freedom of Information Act requests. They show that the FDA considered the cancer risks when approving ranitidine. But Glaxo didn't share a critical study.
>
> "Over the years, the company also backed flawed research designed to minimize concerns and chose not to routinely transport and store the medication in ways that could have eased the problem. Glaxo sold a drug that might harm people, tried to discount evidence of that and never gave anyone the slightest warning."

The report presents evidence indicating that Glaxo — and later GSK — were aware that NDMA could be present in Zantac, both as a result of how it was metabolized in the human stomach and also by naturally occurring even under ordinary storage conditions.

According to the report, ranitidine was first developed by Glaxo scientists in the 1970s, and a U.S. patent for it was granted in 1978. As stated by the report, the process of developing ranitidine and getting it approved was swift.

"They developed ranitidine quickly, and the US Food and Drug Administration reviewed it quickly. Glaxo gave it the brand name Zantac," said Bloomberg Businessweek. It was soon marketed as being "better and safer" than the leading heartburn drug at the time, Tagamet.

However, the warning signs were already there. According to Bloomberg Businessweek, a U.S. government cancer researcher and biochemist, William Lijinsky, had found in 1969 that nitrosamines could form in the stomach, exacerbated by the presence of nitrites, "a common chemical found in cured and grilled meat and in beer and coffee and vegetables" found to be "common causes of heartburn and acid reflux."

Lijinsky's solution to this, presented in published studies and in Congressional testimony in the 1970s, was to limit sodium nitrite levels in food. Already, by the late 1970s, Lijinsky identified roadblocks that were not allowing his warnings to be fully heeded.

"It seems to me that the regulatory agencies have been less than eager to act in the matter of nitrites and nitrosamines," he testified before Congress in 1977. "There has been ample information available, if they had sought it. There is, of course, immense opposition by the manufacturing companies to any change."

According to Lijinsky's wife, Rosalie Lijinsky, herself a genetic toxicologist who recently retired from the FDA, William lost federal funding for his research due to pressure from both the food and pharmaceutical industries.

Nevertheless, the warning signs continued to build up. A 1980 report titled "Glaxo, Ranitidine—Cause for Concern," found that ranitidine could potentially form a potentially dangerous, and cancerous, compound in the stomach.

Glaxo, which was seeking FDA approval for Zantac, prepared for "defensive action" to protect itself from the report's findings. The Bloomberg Businessweek story noted that Glaxo's board never tested ranitidine to see if it might form a nitrosamine compound.

In a 1981 trial in Britain, 11 healthy men who were administered a daily two-dose regimen of ranitidine for four weeks developed more nitrite in their digestive system — meaning that conditions were favorable for the formation of nitrosamines.

These results were deemed inconclusive by Glaxo scientists, who said that "Ranitidine is recommended only for short-term use" — even though most Zantac users took the drug "for months, sometimes years, even decades," according to Bloomberg Businessweek.

Another 1981 study, published in The Lancet by Italian scientist Silvio De Flora, Ph.D., found that when ranitidine was mixed with nitrite, it led to "toxic and mutagenic effects." De Flora later suggested that the consumption of Zantac occur long before or after a meal. However, says Bloomberg Businessweek, "instructions for taking Zantac to prevent heartburn would recommend using it close to mealtime."

De Flora, who told Bloomberg Businessweek that "Pharmaceutical companies do not like this kind of study," said he was quickly approached by Glaxo executives, who then published a follow-up letter in The Lancet attempting to downplay De Flora's findings.

A 1982 study, which infamously became known as the "Tanner study," also found danger. Specifically, this study, conducted by scientist Richard Tanner of rival drugmaker Smith, Kline & French, found that ranitidine when combined with different concentrations of nitrite, formed a cancerous poison that was soon named NDMA.

According to Bloomberg Businessweek, "back in 1982, court documents show, Glaxo kept the study secret. The associate director of clinical research in the U.S. was never told about the Tanner report. The senior medical adviser for gastrointestinal research was unaware of it. So was the FDA."

At the same time, reports Bloomberg Businessweek, "Glaxo also knew of another potentially serious problem with ranitidine. It wasn't always stable. The drug was sensitive to heat and humidity, and when exposed to too much of either could degrade … That creates conditions for NDMA to form in the drug itself."

However, later in 1982, Glaxo officials did not reveal this knowledge to a panel of FDA officials and independent researchers. "The Glaxo scientists disputed the idea that ranitidine could form a nitrosamine under any normal human conditions," according to Bloomberg Businessweek.

By May 1983, the FDA had approved Zantac in a rapid process — and by 1989, it "was worth $2 billion. It accounted for half of Glaxo's sales and 53% of the market for prescription ulcer remedies."

However, problems persisted. In the early 1990s, it was found that the pills were not stable and were changing color while in storage. According to Bloomberg Businessweek, "Discoloration is often a sign that tablets are degrading. In some cases, degradation can cause dangerous impurities to form."

However, Glaxo's solution was to change the color of the pills. At this time, the company was seeking FDA approval for a less potent over-the-counter version of Zantac. This approval came in the spring of 1996.

Nevertheless, issues with discoloration persisted into the last decade. In 2010, Zantac was "tested for impurities that were known to cause … yellow discoloration." Although, according to Bloomberg Businessweek, "NDMA used in labs is yellow," no tests were conducted for this particular substance.

Similarly, when a manufacturing site in China identified problems with "discolored and degraded Zantac tablets" in 2015, GSK sought to downplay the issue, while no testing for NDMA was conducted. Instead, "inappropriate storage" was blamed.

During this period, GSK was fined by regulators in the U.S. and China, but not over Zantac specifically. In 2012, GSK pled guilty and was fined $3 billion "for marketing drugs for inappropriate uses, disregarding safety data and cheating Medicaid," according to the Bloomberg Businessweek report.

And in 2014, "China fined GSK $500 million and deported a top executive for bribing doctors to prescribe its drugs."

Issues with Zantac did not come to a head until September 2019, when the FDA received a document from Valisure, an independent laboratory, which, according to Bloomberg Businessweek, "had found extremely high levels of NDMA in Zantac and several generic versions of ranitidine."

Valisure conducted these tests after NDMA had been found in batches of the blood pressure medication valsartan the previous year. Bloomberg Businessweek reports that Valisure "found NDMA in every version of ranitidine it tested and concluded the problem was inherent to the molecule itself."

Although the FDA issued an alert, it also questioned Valisure's testing methods and conducted its own tests. "Within a month," says Bloomberg Businessweek, "at least two dozen countries pulled ranitidine from stores or halted its distribution." GSK stopped distributing the drug, as did Sanofi.

Ultimately, in April 2020, ranitidine was banned by the FDA. The agency found that "NDMA levels increase in ranitidine even under normal storage conditions … And NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers."

However, says Bloomberg Businessweek, the FDA has not shared specifics in any published paper about what its tests detected. Instead, these findings were revealed "during a monthly lecture series called FDA Grand Rounds," in October 2021: one tablet of ranitidine contained "almost four times the FDA's limit in any drug" when initially tested.

Nevertheless, in June 2021, the FDA said there were "no consistent signals" that Zantac increases cancer risk and that such links that were found in outside research papers were not conclusive. Bloomberg Businessweek says this "is now a regular part of Glaxo's public-relations and, presumably, legal defense."

A statement provided by GSK to Fierce Pharma in response to the Bloomberg Businessweek article says it "presents an incomplete and biased presentation of the facts surrounding the Zantac (ranitidine) litigation."

"Patient safety is the highest priority for GSK, and the company categorically refutes any allegation of having covered up data regarding the safety of ranitidine," the statement adds. "The safety of ranitidine has been thoroughly evaluated over the past 40 years."

Thousands of Zantac-related lawsuits pending despite setbacks

The Bloomberg Businessweek report states that "More than 70,000 people who took Zantac or generic versions of it are suing the company in U.S. state courts for selling a potentially contaminated and dangerous drug," with the first of these trials set to begin later this month in the Superior Court of California, County of Alameda.

Other companies that sold Zantac, including Pfizer, Sanofi and generic manufacturers, are also facing lawsuits.

There have been some setbacks for plaintiffs, however. According to the Bloomberg Businessweek report, a December 2022 ruling, by the U.S. District Court for the Southern District of Florida, "dismissed thousands of federal lawsuits that had been consolidated in her courtroom for pretrial proceedings."

U.S. District Judge Robin Rosenberg found there is "no widespread acceptance in the scientific community of an observable, statistically significant association between ranitidine and cancer." Lawyers for the plaintiffs plan to appeal.

GSK is hanging its hat on this ruling, according to Bloomberg Businessweek. In a statement, Kathleen Quinn, a spokesperson for the company, said, "The court's view is consistent with the position that GSK and other co-defendants have taken throughout this litigation."

And in a statement following the Florida federal court ruling, GSK said it was glad that "unreliable and litigation-driven science did not enter the federal courtroom."

Fierce Pharma reports that following this ruling, not just GSK but "Pfizer, GSK, Sanofi and Boehringer Ingelheim are now able to wash their hands of thousands of Zantac-related lawsuits," as about 50,000 claims were taken "off the drugmakers' plates."

And according to Law360, on Feb. 7, the same Florida judge issued a new ruling which will not allow tens of thousands of Zantac lawsuits to be combined.

This ruling was made on the basis that the lawsuits in question had signed up for "court-created registry of claims in the multidistrict legislation" that was "abandoned" following the December 2022 decision.

In this new ruling, Judge Rosenberg also provided some insights into the appeals that were filed against the December 2022 decision, stating that "claimants in the registry are still now required to file their cases individually in federal court in order for their claims to be considered timely," according to Law360.

However, as reported by Bloomberg Businessweek, "GSK does still have to fight the tens of thousands of cases waiting in state courts, where judges aren't bound by the federal court's ruling," adding that "GSK could face years of lawsuits in California, Delaware and other states, with the possibility of billions in damages."

Law360 reported Jan. 26 that despite the December 2022 Florida ruling, "New York's Litigation Coordinating Panel on Thursday consolidated more than 40" Zantac lawsuits. Attorneys from Napoli Shkolnik PLLC, one of the firms representing plaintiffs in the lawsuits, described this as "a welcome alternative" to the Florida multidistrict litigation.

In the forthcoming Alameda County court case, GSK "is expected to urge" the court "to limit what expert testimony jurors can hear," reports Reuters.

The plaintiff in that case, James Goetz, says he developed bladder cancer from taking Zantac over a period of many years. According to Bloomberg Businessweek:

> "Goetz was 60 in 2017 when he was diagnosed with bladder cancer. That in and of itself wasn't too unusual; 60 is about the age this particular cancer is often diagnosed in men. Smokers get bladder cancer, but Goetz hadn't smoked since he was 22. His job hadn't exposed him to any potentially harmful chemicals. It was perplexing, but he had no reason to think his getting cancer was anything other than random.
>
> "When Zantac was recalled, he kept four bottles he'd already purchased. They're in the freezer in the office of one of his attorneys, Brent Wisner, as are leftover pills from Russell. Tests showed that one of Goetz's pills is contaminated with 3,000ng of NDMA, Wisner says; one of Russell's has more than twice as much. Wisner says he's invited GSK to test the tablets, but the company hasn't done so."

Goetz's cancer has returned in aggressive form, necessitating surgery and dialysis. His bladder and prostate were removed, along with 20 feet of his intestines. He later suffered sepsis, kidney stones and kidney failure. His lawsuits against Boehringer Ingelheim, Pfizer and Sanofi were settled in December 2022, but his GSK case continues.

Depositions taken during the discovery process, brought to the public eye by Bloomberg Businessweek, have been revealing. A former senior medical adviser to Glaxo, when asked during a June 2021 deposition whether Glaxo had ever tested for the presence of NDMA in Zantac, answered, "Not to my knowledge."

In a May 2022 deposition, Andrew Whitehead, who had been director of second-generation research and development for the company, testified that "it would have been known in the '80s as part of the development" of Zantac that ranitidine would degrade in high temperature conditions.

And a May 2021 deposition, Fred Eshelman, formerly Glaxo's associate director of clinical research when Zantac was developed, agreed with a lawyer for the plaintiffs that "it is completely unheard of in the industry to go that fast" — referring to the clinical development of ranitidine.

More drugs under scrutiny for potential presence of nitrosamines

As the lawsuits against the former manufacturers of Zantac continue, increased scrutiny of medications for the potential presence of nitrosamines has followed.

USA Today reports that the FDA "has asked drugmakers to evaluate all products for any risk they might contain nitrosamines," adding that "Companies that identify any such risk must conduct follow-up testing, report changes and take action" by Oct. 1.

"We continue to closely evaluate this type of impurityand will continue to investigate and monitor the marketplace and manufacturing efforts to help ensure the availability of safe, quality products for U.S. consumers," stated FDA spokesman Jeremy Kahn.

According to USA Today, in recent years, several drugs have been recalled due to the presence of nitrosamines, including diabetes medication metformin, anti-smoking medication Chantix, and blood pressure, heart and kidney medications losartan, quinapril (sold as Accupril) and valsartan.

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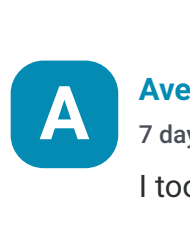

Michael Nevradakis, Ph.D.

Michael Nevradakis, Ph.D., based in Athens, Greece, is a senior reporter for The Defender and part of the rotation of hosts for CHD.TV's "Good Morning CHD."

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Best Newest Oldest

Ave Bkr
7 days ago
I took this garbage for some time... stopping it was the best decision I ever made!!!
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gnt
7 days ago
Of course it took only 40 years and something like 70,000 lawsuits, and unknown numbers of dead and injured from this poison, for the truth to come out. It's okay though, the government is still telling us that they want to keep us safe by "recommending" we wear a filthy face covering over our mouths.
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brbg → gnt
5 days ago
Either the government is highly invested in Big Pharma or they don't care a whit about people. I swear half of them are globalists and go along with Bill Gates' plan to cull the world's population by 75%.
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E_via
7 days ago
Trust the science. Safe and effective. Listen to the experts. Government is here to help you. Wash, rinse, repeat.
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Someone should check the bank accounts, including offshore, of this Florida judge, just in case they find something 'funny'..
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vgupta123
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Well, here is another surprise after 40 years: Tylenol causes autism and ADHD. Lawsuits are piling up. But there is no discovery yet. So we don't know for how long the manufacturers have known this.
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jann → vgupta123
7 days ago
I heard about problems with Tylenol causing liver damage through word of mouth when my son was a baby. His pediatricians never mentioned this.
3 0 Reply • Share ›

vgupta123 → jann
6 days ago
Liver damage from (too much) Tyelnol mainly affects adults. That issue has been known for 40 years.
Autism and ADHD from Tylenol mainly affects babies. This issue has been known for about 10 years.
1 0 Reply • Share ›

jann → vgupta123
4 days ago
He was vaccine injured starting with his first dose of polio at two months. Of course, I was told to give him Tylenol for fever. He later developed jaundice which can be caused by a damaged liver. He also had ADHD and ASD. Let's not pigeon hole factors. That's the medical establishment does.
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jann → jann
5 days ago
He was vaccine injured starting with his first dose of polio at two months. Of course, I was told to give him Tylenol for fever. He later developed jaundice which can be caused by a damaged liver. He also had ADHD and ASD. Let's not pigeon hole factors.
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brbg → vgupta123
5 days ago
I remember reading an article by a former scientist for a Pharmaceutical company. In it he wrote that he was tasked to look into any connection between autism and the MMR vaccine. He said he found a definite connection. Then his boss told him to destroy his research. His boss then quit and took an executive position with the FDA.
1 0 Reply • Share ›

jann
7 days ago
I'm going to print and paste this article in front of drug chains and add "And you still believe the FDA?"
4 0 Reply • Share ›

Carrie Lavine
4 days ago
And some people wonder why they havent found a cure for cancer-its big industry-when the most simple cures for indigestion like ginger tea or peppermint r politicized.
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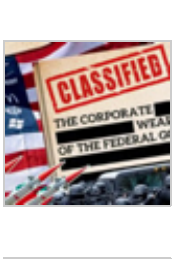

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Pharmaceutical companies are criminal organizations. It's all about money without a concern for the public.

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Kitty Ca'at
6 days ago

Criminal charges against the people responsible for this type of ongoing murderous fraud is the only stick that will stop it.

2 0 Reply • Share ›

> **Beatrice** → Kitty Ca'at
> 6 days ago
>
> I agree but the problem is that these corporations are structured in such a way that finding a source of accountability is almost impossible. Plus, the morons or the bribed regulators that conduct an investigation will most likely not look very hard for evidence of malpractice or misconduct.
>
> 2 0 Reply • Share ›

EA vvn
4 days ago

And the question i have is ...
When will the top executives and "researchers and Scientists" of GSK and those at FDA who approved this toxic poison go to JAIL ?

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